PSJ3

Exhibit 450B

HDMA Board of Directors

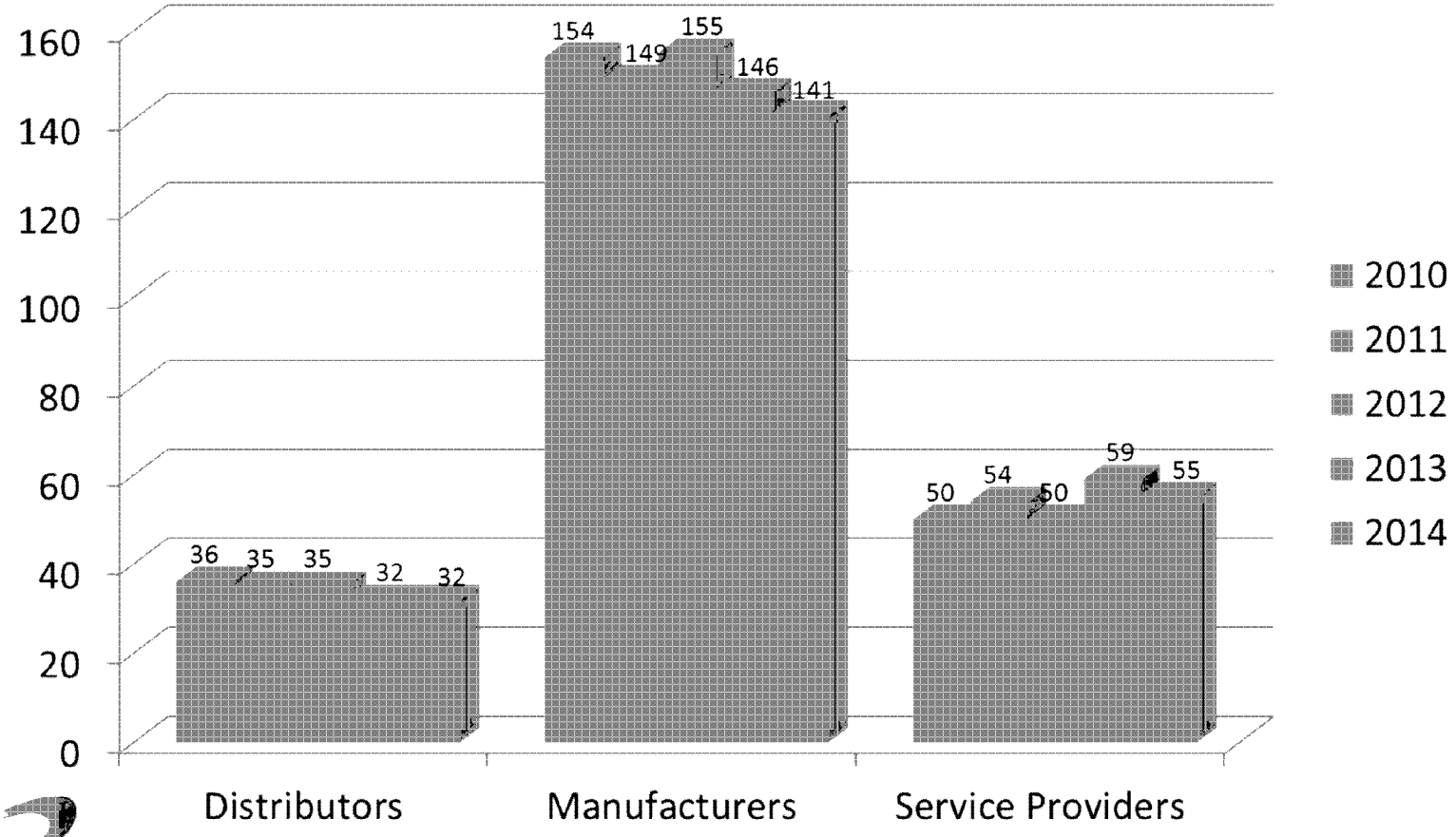
Tab B – Membership Update

Membership Update

June 1, 2014

HDMA
Healthcare Distribution Management Association

Member Companies by Type



CHDMA
Healthcare Distribution Management Association

Activity in 2014

Distributors

- Added Metro Medical; Frank W. Kerr membership in process
- BDI Pharma resigned

Manufacturers

- Added 13 new members with total dues of $75,546
- Lost 18 members with dues of $177,192
  - 7 of the 18 were acquisitions

Service Providers

- Added 4 new members (1 additional pending)
- Lost 10 companies

HDMA
Healthcare Distribution Management Association

HDMA 2014 Membership Report

As of May 22, 2014

Summary Dues Report

	2014			2013	2012	2011
	Actual	Budget	% to Budget	Actual	Actual	Actual
Active Distributors	$4,782,140	$4,789,950	99.8%	$4,806,950	$4,735,907	$4,628,150
Manufacturers	$2,631,470	$2,657,486	99.0%	$2,635,821	$2,740,022	$2,574,816
Service Providers	$341,650	$351,875	97.1%	$358,750	$327,090	$367,500
Int'l Distributors	$5,225	$5,500	95.0%	$5,958	$6,489	$4,400
	$7,760,485	**$7,804,811**	**99.4%**	**$7,807,479**	**$7,809,508**	**$7,574,866**

Current Gap: -$44,326

Active Distributor Members

2014 Renewals (paid)	New Members	Resigned	Acquired / Merged	Total Members	2013 Members
27	1	(1)	0	32	32

New Members

- Metro Medical
- **NOTE:** Frank W. Kerr membership application is pending. They will attend BLC provisionally and the application process will be finalized shortly after. They are not included in the above numbers.

Acquired / Merged

Resignation

- BDI Pharma

Associate Manufacturer Members

2014 Renewals (paid)	New Members	Invoiced / Sales Reports	Resigned	Acquired / Merged	Total Members	2013 Members
123	13	5	(11)	(7)	141	146
			-$57,147	-$120,045		

New members

- Camber Pharmaceuticals, Inc.,
- Citron Pharma, LLC
- Claris Lifesciences Inc.
- Colgate Oral Pharmaceutical, Inc.
- Gensco Laboratories
- INSYS Therapeutics, Inc.
- Nipro Diagnostics, Inc. (HBW membership)
- Medac Pharma
- Recordati Rare Diseases Inc.
- Sigma-Tau Pharmaceuticals, Inc.
- Tolmar Pharmaceuticals, Inc.
- Unichem Pharmaceuticals USA, Inc.
- VitaMedMD/TherapeuticsMD

Resignations / Terminations

- AVEO Oncology
- Briggs Healthcare
- Fera Pharmaceuticals
- HUMCO Holding Group, Inc.
- Lundbeck
- Midlothian
- Numark
- Omeros
- Optimer
- PBM Pharmaceuticals
- Valeritas

Acquired / Merged

- Actient (Auxilium)
- Aptalis (Forest)
- Hi-Tech Pharmacal (Akorn, Inc.)
- Millennium (Takeda)*
- Onyx (Amgen)
- Santarus (Salix)
- URL (Sun Pharma)

(- Companies at Dues Cap)*

Allied Service Provider Members

2014 Renewals (paid)	New Members (paid)	Invoiced	Resigned	**Total Members**	2013 Members
42	4	1	(10)	**55**	59
			-$75,000		

New Members

- BuzzeoPDMA, A Cegedim Company
- Covectra, Inc.
- Edifecs, Inc.
- Sharp Packaging Solutions

Resigned

- Deloitte Consulting
- Dohmen Life Science Services
- FastPoint
- One World Inc.
- Optel Vision
- Pharma Compliance
- PharmaReturns
- TAKE Solutions
- Temptime
- Wholesale Alliance

Note: One new member is among those that have been invoiced.

Note: Crecon Research was reclassified as an Allied member from International.

(- Companies at Dues Cap)*

HDMA Board of Directors

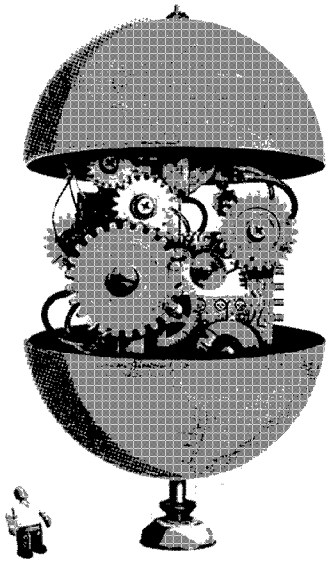
Tab C – Meetings, Conferences & Education Programs

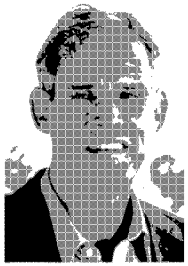
Meetings, Conferences & Education Programs

HDMA
Healthcare Distribution Management Association

2014 BUSINESS AND LEADERSHIP CONFERENCE

Healthcare Distribution Industry's Signature Annual Event * One-on-One Business Appointments * Industry Recognition * Women's Executive Forum

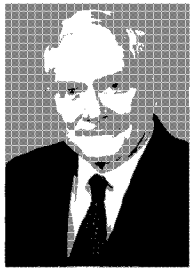




Innovation and the Future of Healthcare

Dr. Eric J. Topol

Author, *The Creative Destruction of Medicine*; and Director, Scripps Translational Science Institute



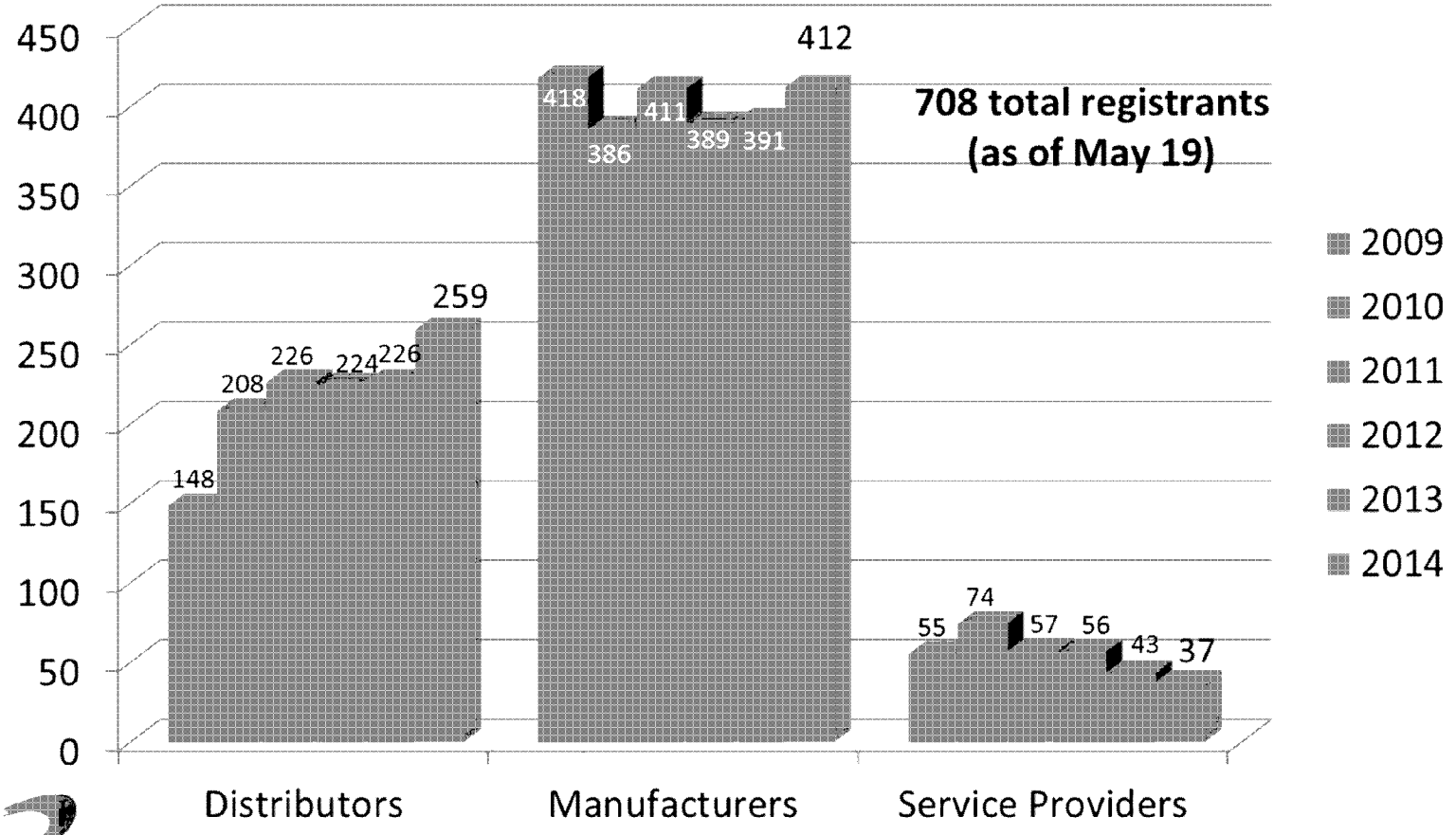
Duty

Robert Gates

Secretary of Defense (2006–2011); Author, *New York Times* Bestseller, *Duty: Memoirs of a Secretary at War*

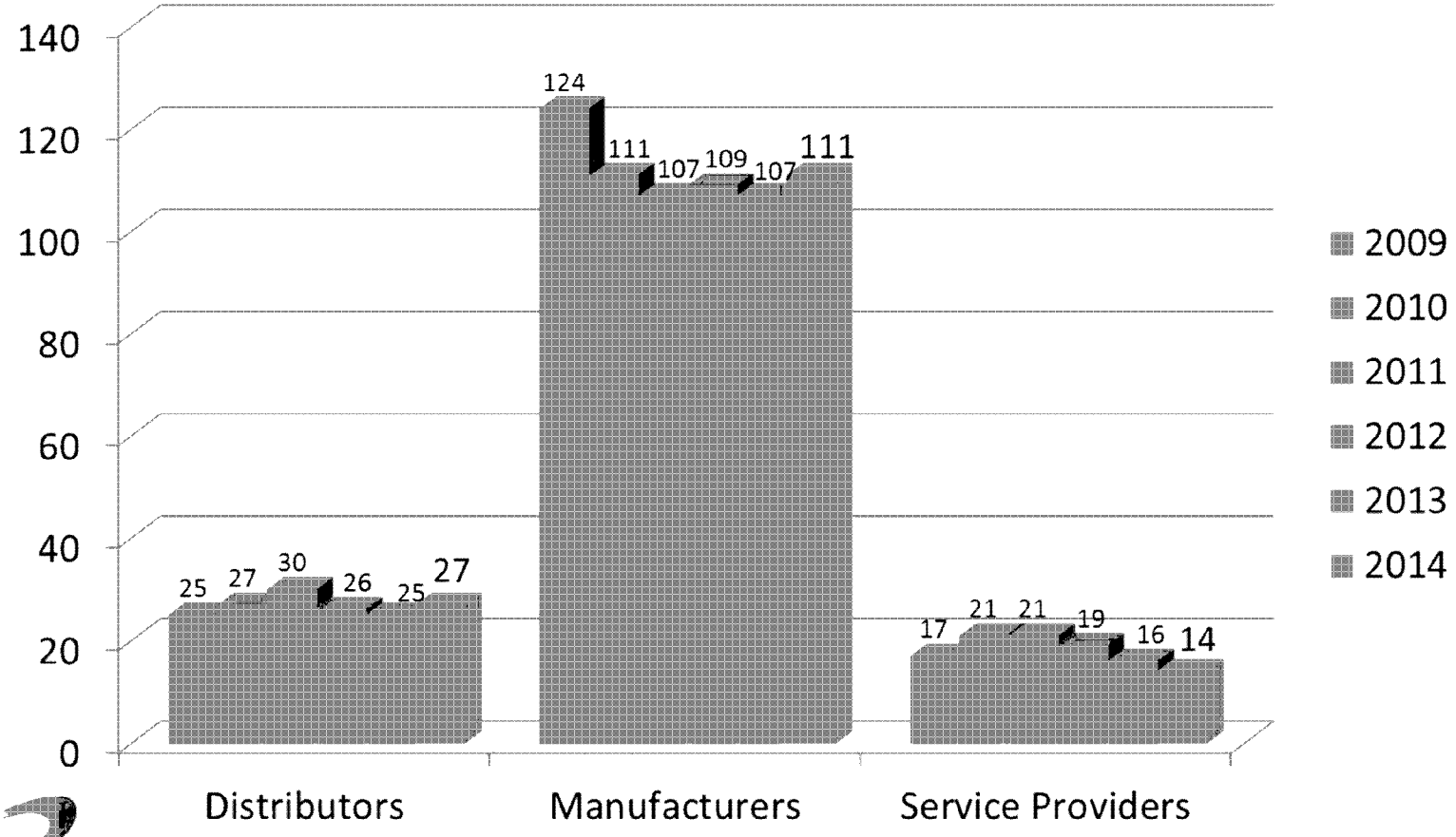
CHDMA

BLC Attendees by Member Type



CHDMA
Healthcare Distribution Management Association

BLC Companies by Member Type



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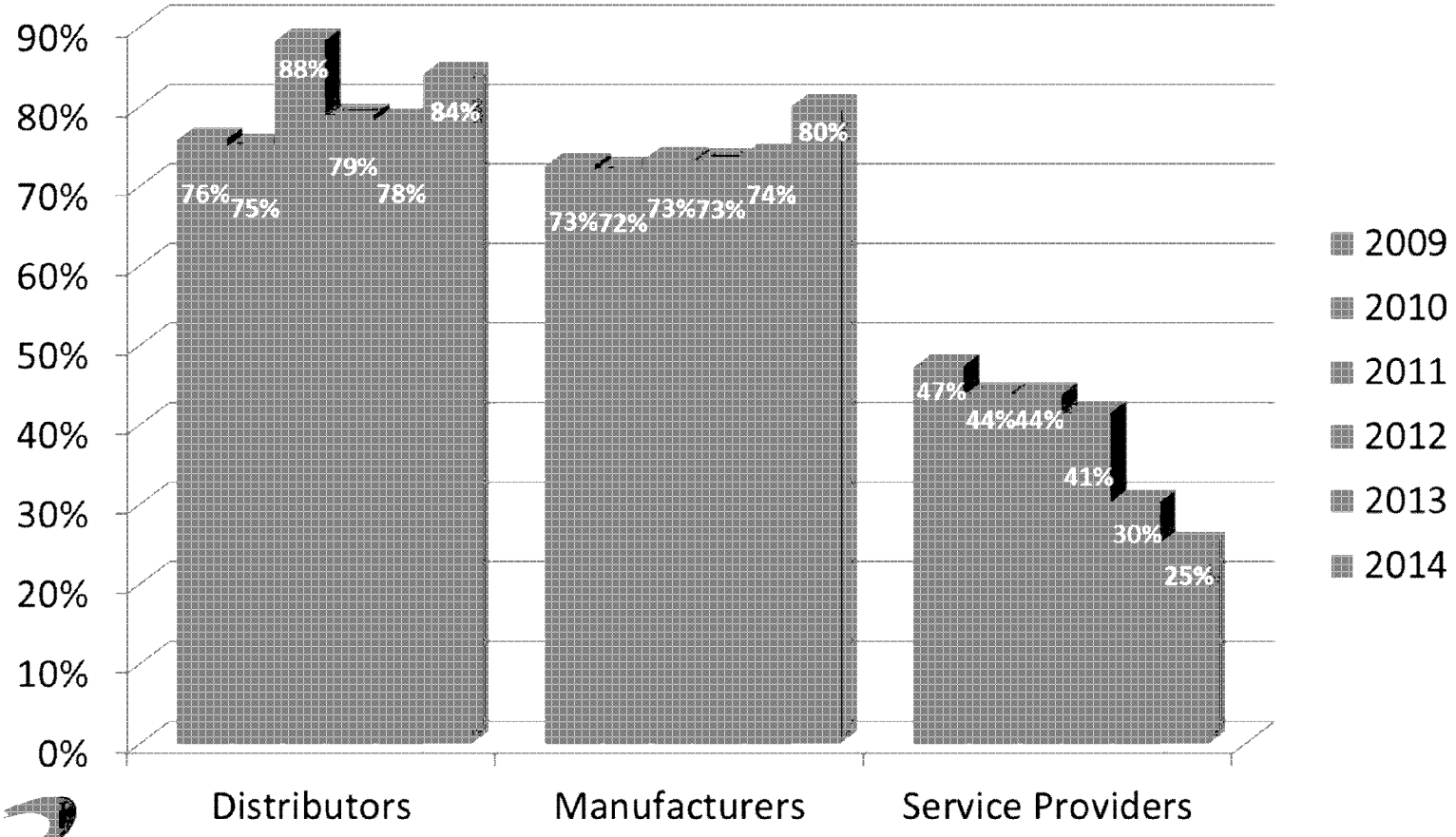
BLC Companies by % of Members



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32	137	55
TOTAL CURRENT MEMBERS		

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION

Annual Board & Membership Meeting

Sunday, Sept. 28 – Wednesday, Oct. 1, 2014
The Montage | Laguna Beach, California

- Executive Committee and Board Meetings
- General Sessions
- One-on-Ones
- Informal Networking

HDMA
Healthcare Distribution Management Association

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION

Annual Board & Membership Meeting

2014 Sponsors

amneal PHARMACEUTICALS

APOTEX ADVANCING GENERICS

astellas

Eisai

Lilly

Mallinckrodt

Mylan Seeing is believing

Takeda

TEVA Pharmaceuticals

UPSHER-SMITH Pharmaceuticals Since 1919

HDMA Healthcare Distribution Management Association

ABMM Speakers Confirmed

Doug Long

Vice President, Industry Relations, IMS Health, Inc.

KT McFarland

FOX News' National Security Analyst and Former Nixon, Ford, Reagan Staffer

David Wasserman

House Editor, "The Cook Political Report"

Paul Lazarus

Film director, producer, writer; Director of documentary "Slingshot"

HDMA
Healthcare Distribution Management Association

2014 Education Seminars & Webinars

Putting HDMA HBW Research Into Action: Paths to Success with Independent Pharmacies

Webinar
February 27, 2014

FDA Perspectives on Implementation of the Drug Supply Chain Security Act

Webinar Sponsored by Frequentz
April 7, 2014

Communicating Credibly

Webinar in Conjunction with WEF and Sponsored by EXP Pharmaceutical Services Corp.
April 30, 2014

Front-End Forum

June 2, 2014
JW Marriott Desert Ridge, Phoenix, Ariz.

Contract and Chargebacks Seminar: Perspectives on Process Improvement

October 15-16, 2014
Hotel du Pont • Wilmington, Del.

Traceability Seminar

November 10-12, 2014
Renaissance Arlington Capital View Hotel • Arlington, Va

Specialty Pharmaceutical Supply Chain Issues and Trends Seminar

Presented by CENTER FOR HEALTHCARE SUPPLY CHAIN RESEARCH, HDMA KNOWLEDGE PARTNER

November 12-13, 2014
Renaissance Arlington Capital View Hotel • Arlington, Va

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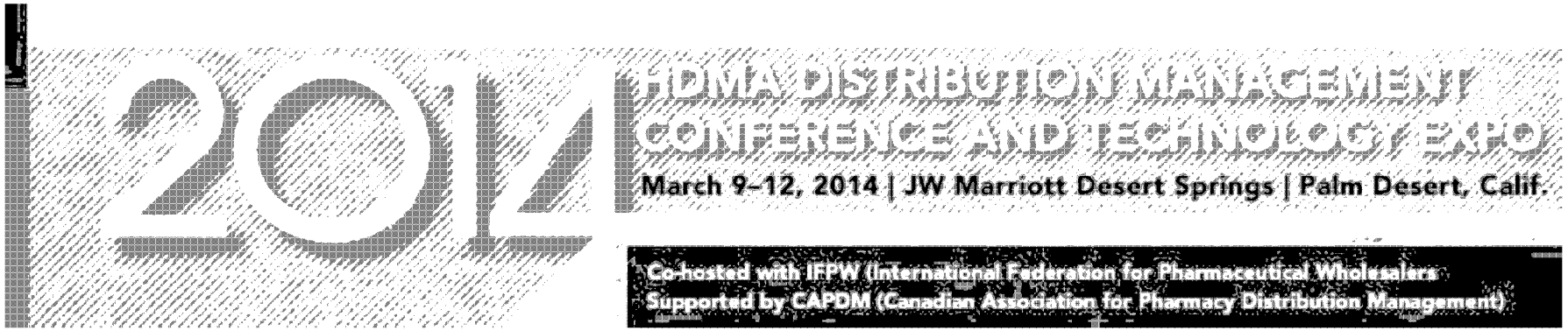
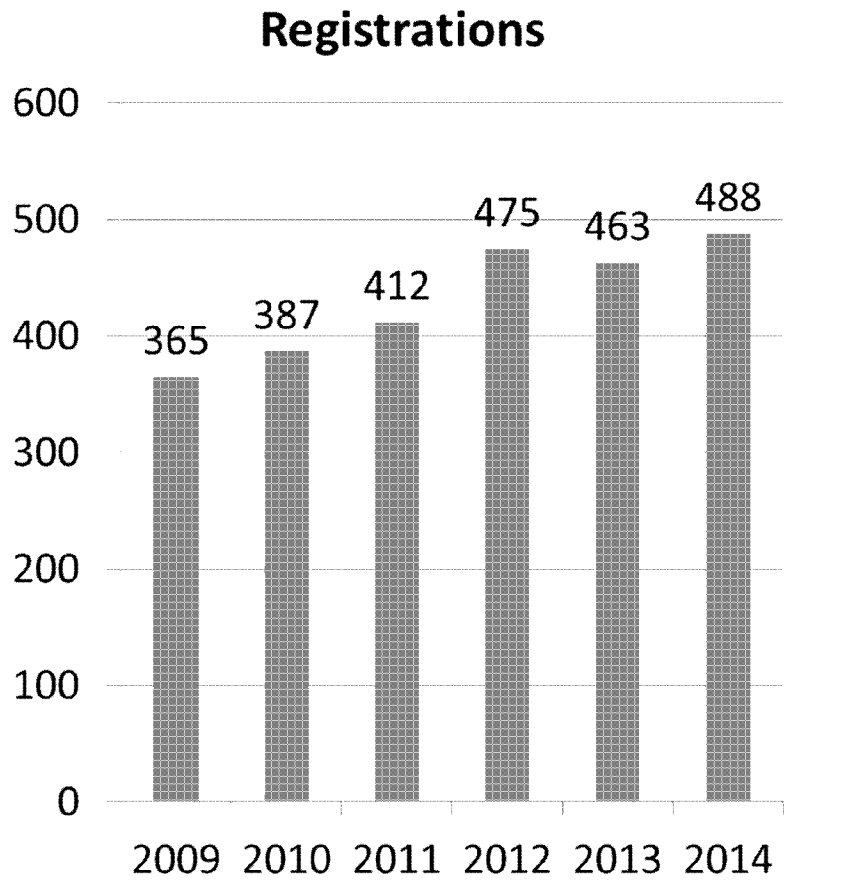


- Select from nearly **30 business, policy and technology** breakout sessions
- Engage with more than **40 exhibitors and solution providers** at the Technology Expo
- Hear from nearly **50 industry knowledge leaders** during education and general session presentations

▸▸ www.HealthcareDistribution.org/dmc.asp

DMC 2014

- Attendance was strong in 2014 – highest in 6 years
- Sold out exhibit floor – 3rd year!
- 4th year featuring "Specialty Distribution" track
- 3rd year partnering with IFPW on "International" track and 2nd with support from CAPDM
  - At least 23 international attendees



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Save the Date – 2015 DMC

Sunday, March 8 - Wednesday, March 11, 2015
Distribution Management Conference and Technology Expo
JW Marriott Orlando Grande Lakes • Orlando, Fla.

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- First HDMA education program outside U.S.; held in cooperation with China Association of Pharmaceutical Commerce (CAPC)
- Agenda focused on supply chain issues with international significance
  - Global Supply Chain Trends (based on IBM study of chief supply chain officers)
  - Global Standards (GS1)
  - Serialization & Traceability (McKesson, J&J, Jointown Pharmaceutical Group)
  - International Regulatory Cooperation
  - Advances in Cold Chain Management (Sinopharm)
  - Managing Consolidation (China Resources)
  - Enhancing Supply Chain Security: Rx360 Case Study (AstraZeneca)

CHDMA
Healthcare Distribution Management Association

HDMA Board of Directors

Tab D – Center for Healthcare Supply Chain Research

CENTER FOR HEALTHCARE SUPPLY CHAIN RESEARCH
HDMA KNOWLEDGE PARTNER

To: HDMA Board of Directors

From: Karen J. Ribler
Executive Vice President and COO
Center for Healthcare Supply Chain Research

Date: May 21, 2014

Re: Center for Healthcare Supply Chain Research Activities

The following are highlights of the Center's activities for the first half of this year:

6th Annual CEO Roundtable Fundraiser

A very successful CEO Roundtable Fundraiser was held in New York City, April 1st. The guest of honor, George Paz, Chairman and CEO Express Scripts, Inc. provided a narrative on his upbringing, management philosophy and fondness for his country, as well as his perspective on a range of issues shaping the pharmaceutical supply chain today and in the future. During the evening attendees received a copy of the Center's 2013 Annual Report. The fundraising event netted the Center ~ $390,000.

Completed Research

The Center released the *2013 Specialty Pharmaceutical Distribution: Facts, Figures and Trends* in March, sales of which reflect high interest in this industry segment by manufacturers, distributors, consultants, analysts, higher education and service providers. Data from the book has been cited in various articles, as well as on slide presentations at the most recent Armada Summit.

Research Underway

Presently data is being collected for the 2014 *HDMA Factbook* and the 2014 edition of the *Specialty Pharmaceutical Distribution: Facts, Figures and Trends*, both of which are scheduled for a Fall release. In addition, the Center is working on two research studies, *Global Security and Importation* and *Biosimilars: Lessons Learned from Europe and Strategies for the U.S. Market* that are scheduled to be released before the end of the year.

Center Board of Directors

Michael Conley, Executive Director, USMM & MA Wholesale/Retail Channels and Pharmacy Affairs, Novartis Pharmaceuticals Corporation has been nominated to serve on the Center's Board.

HDMA Board of Directors

Tab E – HDMA PAC Presentation

HDMA PAC
POLITICAL ACTION COMMITTEE

2014 Update

HDMA PAC
POLITICAL ACTION COMMITTEE

HDMA PAC

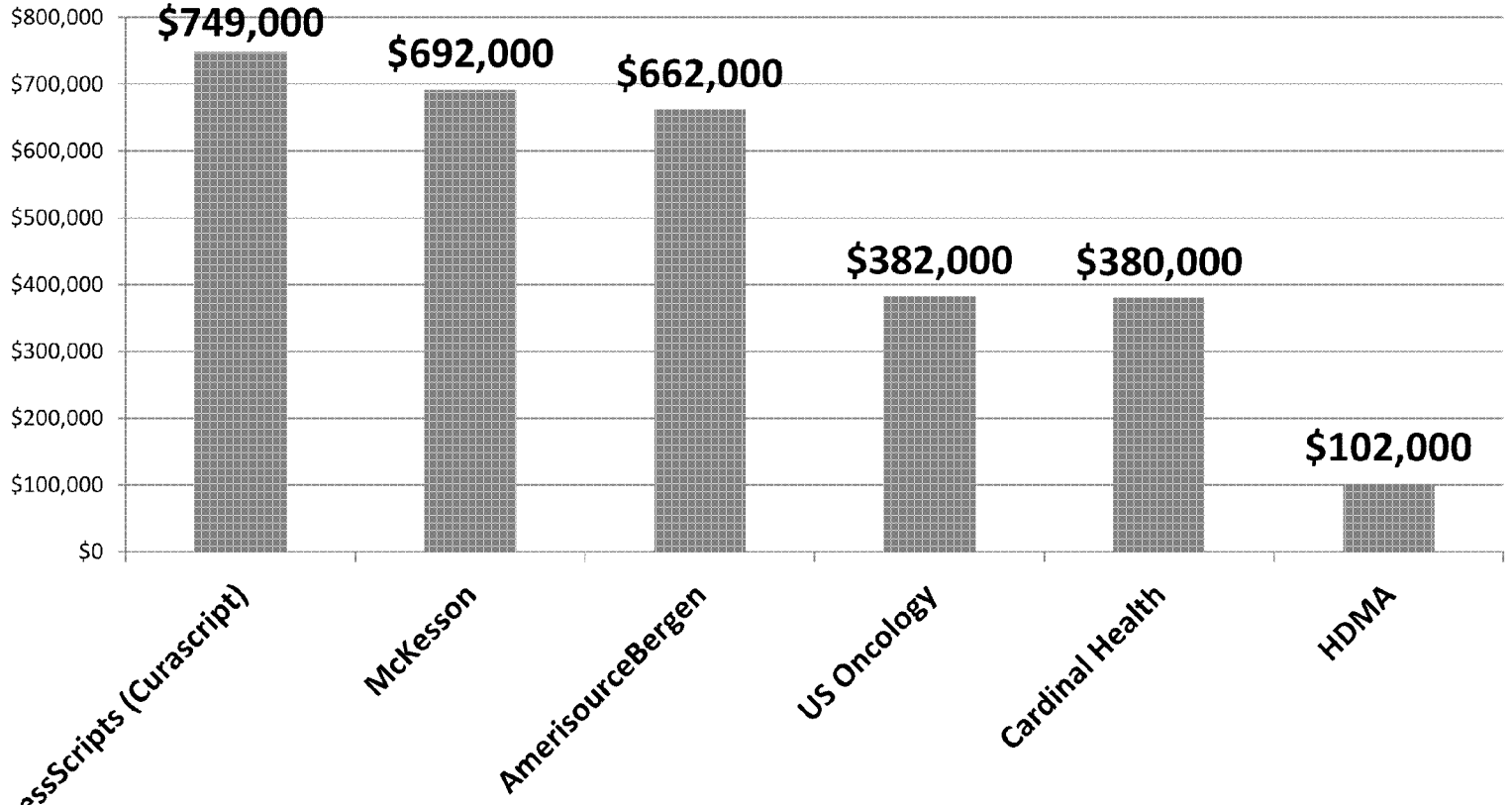
- The HDMA PAC is a voluntary, nonpartisan, political action committee established to support federal candidates for elective office.

- The HDMA PAC is supported exclusively through personal contributions from member company executives and HDMA staff.

HDMA PAC
POLITICAL ACTION COMMITTEE

HDMA Member Company PACs

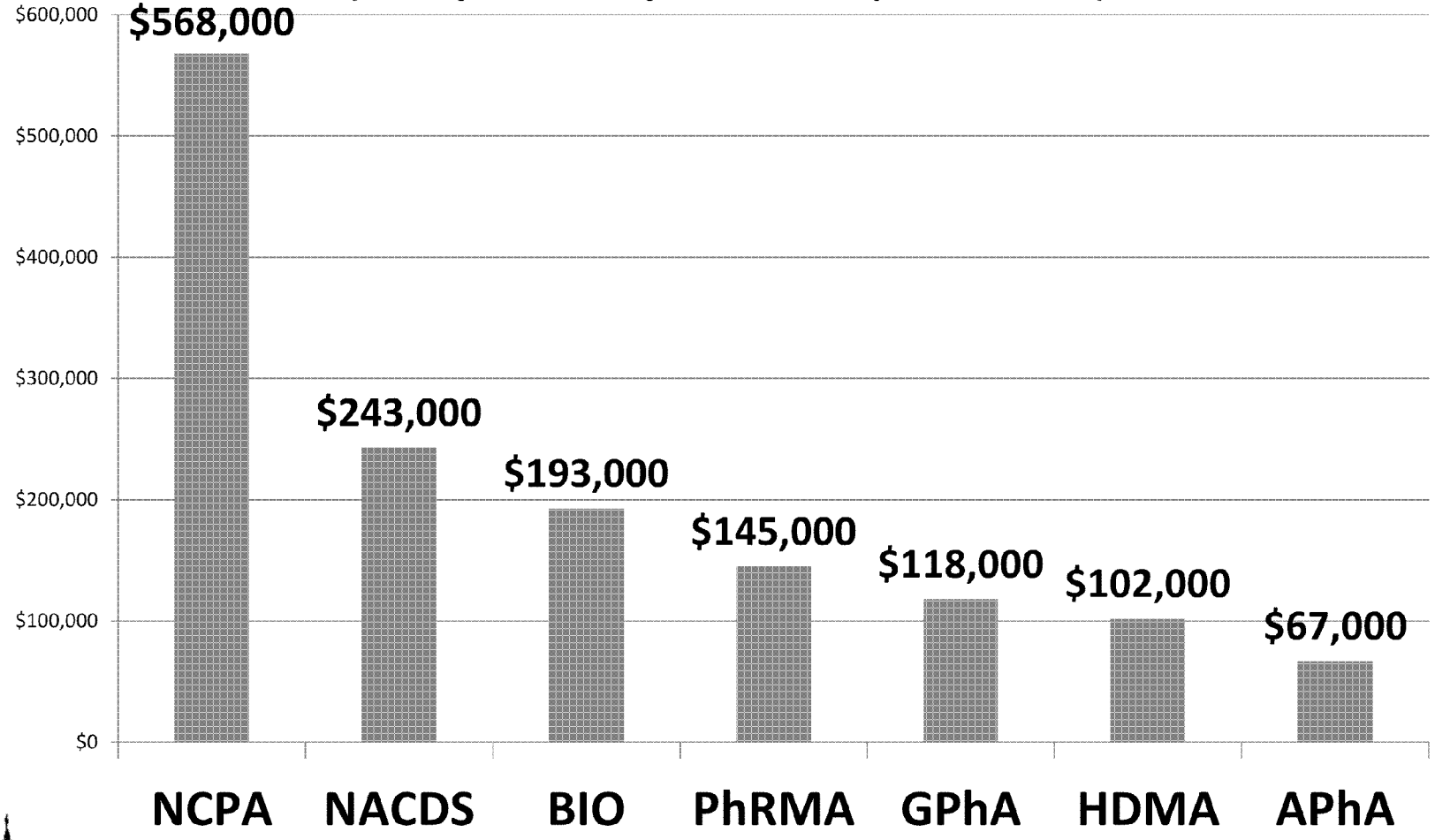
(Receipts January 1, 2013 – April 30, 2014)



HDMA PAC
POLITICAL ACTION COMMITTEE

Industry Association PACs

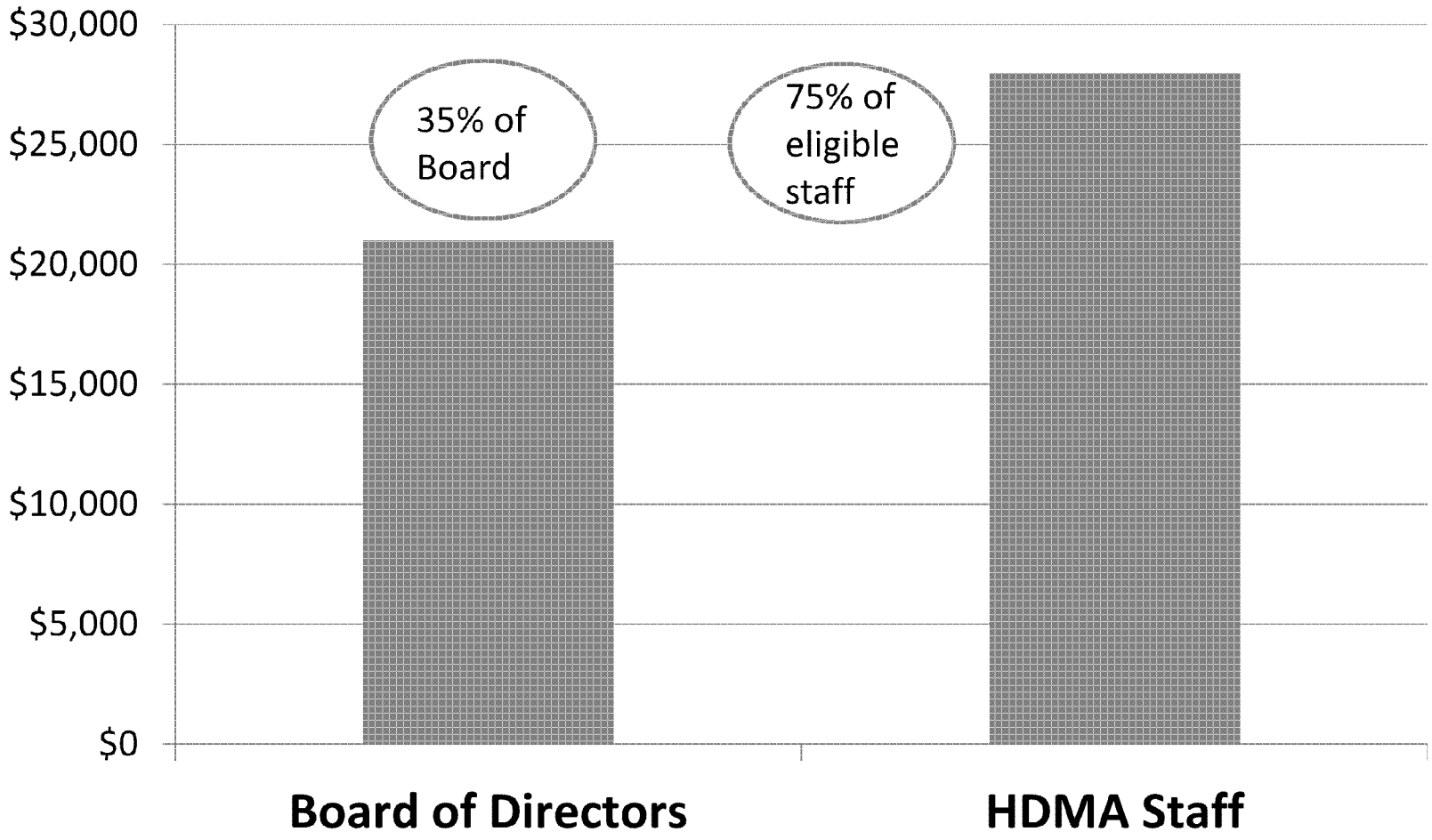
(Receipts January 1, 2013 – April 30, 2014)



HDMA PAC
POLITICAL ACTION COMMITTEE

HDMA PAC

(2014 receipts)



HDMA PAC
POLITICAL ACTION COMMITTEE

Thank you to our 2014 Board contributors

The Chairman's Circle ($3,000-$5,000)

- Ken Couch, Smith Drug Co.
- Dave Neu, AmerisourceBergen Corporation

The President's Circle ($1,000 - $2,999)

- Dawn Boyter, Richie Pharmacal Co.
- Maria Burns, Burlington Drug Co.
- Gregory Drew, Value Drug Co.
- Sam Lazich, DMS Pharmaceutical Group, Inc.
- David Moody, Mutual Wholesale Drug Co.
- Tony Rattini, Miami-Luken, Inc.
- George K. Richards, Capital Wholesael Drug Co.

HDMA PAC
POLITICAL ACTION COMMITTEE

HDMA Board of Directors

Tab F – IMS DEA Data Solution

Materials for this section

will be presented at the meeting.

HDMA Board of Directors

Tab G – Discussion Issues

HDMA Board of Directors Meeting

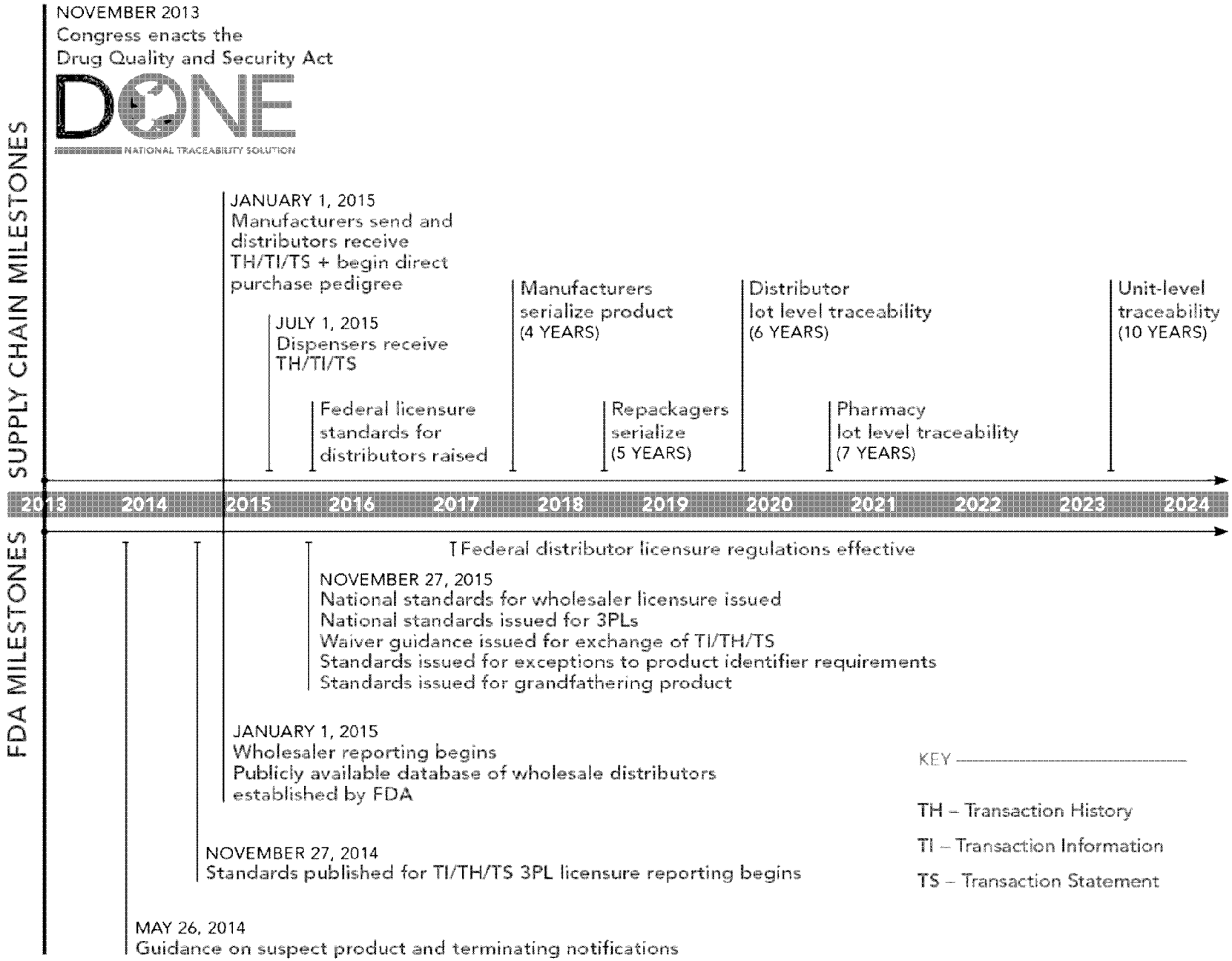
Discussion Issues

June 1, 2014

HDMA
Healthcare Distribution Management Association

Pedigree/Traceability Implementation

HDMA
Healthcare Distribution Management Association


SUPPLY CHAIN MILESTONES
NOVEMBER 2013
Congress enacts the
Drug Quality and Security Act
DONE
NATIONAL TRACEABILITY SOLUTION
JANUARY 1, 2015
Manufacturers send and
distributors receive
TH/TI/TS + begin direct
purchase pedigree
JULY 1, 2015
Dispensers receive
TH/TI/TS
Federal licensure
standards for
distributors raised
Manufacturers
serialize product
(4 YEARS)
Repackagers
serialize
(5 YEARS)
Distributor
lot level traceability
(6 YEARS)
Pharmacy
lot level traceability
(7 YEARS)
Unit-level
traceability
(10 YEARS)
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
FDA MILESTONES
Federal distributor licensure regulations effective
NOVEMBER 27, 2015
National standards for wholesaler licensure issued
National standards issued for 3PLs
Waiver guidance issued for exchange of TI/TH/TS
Standards issued for exceptions to product identifier requirements
Standards issued for grandfathering product
JANUARY 1, 2015
Wholesaler reporting begins
Publicly available database of wholesale distributors
established by FDA
NOVEMBER 27, 2014
Standards published for TI/TH/TS 3PL licensure reporting begins
MAY 26, 2014
Guidance on suspect product and terminating notifications
KEY
TH – Transaction History
TI – Transaction Information
TS – Transaction Statement

Implementation

- Ongoing - HDMA staff and member Workgroups/Committees
  - Cross section of Operations, Regulatory, IT, Compliance and Government Affairs
  - Monthly meetings, weekly+ calls
- FDA interactions
- Working with other stakeholder groups: PDSA, NACDS, etc.

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First Critical Date for Wholesale Distributor Compliance

January 1, 2015

- Must have Suspect and Illegitimate Product "systems" (quarantine, investigate, notify, etc.)
- Must report to FDA
  - All state licenses
  - "any significant disciplinary actions"
  - Reporting must "be regularly updated"
- **Receive &Transmit TI, TH, TS**

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Healthcare Distribution Management Association

Upcoming FDA Regulations/Guidances

2014

- Suspect and Illegitimate Product guidance - 5/27
- State license reporting - TBD
- Draft standards/guidance for TI/TH/TS – 11/27
  - Please publish early!

2015

- Wholesale distributor licensure standards – proposal (tentative) early 2015; final 11/27
- Guidance for TI/TH/TS waivers, identifier exceptions, exemptions, grandfathering - 11/27

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Healthcare Distribution Management Association

2014 HDMA Accomplishments to Date

Date	Activity
01/17/14	HDMA letter to states on DSCSA and preemption
02/10/14	Briefed FDA on Distribution 101
02/24/14	Submitted letter to FDA with S&I product recommendations
04/18/14	Input to FDA on their Request for Info on Data Exchange (TI/TH/TS)
04/30/14	Completed ASN Guideline Revision
05/8-9/14	Participated in FDA Workshop on Data Exchange
05/17-21/14	DSCSA discussions at NABP
Almost done	"Transaction Scenarios" defining: when to pass TI/TH/TS, what to pass, to whom, what format
Almost done	Revision of New Product Introduction Form
Due 6/9/14	Workshop follow-up comments for FDA
Ongoing	PDSA participation
Ongoing	State interactions

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What's Next in 2014?

Planned

- Continue to ID issues, definitions, PDSA participation, etc.
- Input to FDA on
  - How to report state licenses
  - Structure of the state licensure standards
- FDA meeting on Transaction Scenarios (requested)

Potential/Tentative

- Public release of Transaction Scenarios?
- Further educational info HDMA members? Customers?
- Revise ASN guidance?

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Drug Abuse and Diversion

HDMA
Healthcare Distribution Management Association

Significant Activity on Drug Abuse

There have been seven Congressional hearings in the past two months where some aspect of the drug abuse issue was discussed. Significant attention now on growing heroin epidemic and the linkage to prescription drug abuse.

House Hearings:

E&C Health Subcommittee
E&C Oversight and Investigations
Judiciary Committee
Appropriations Commerce, Justice & Science Subcommittee

Senate Hearings:

Judiciary Committee
Veterans Affairs Committee
Senate Caucus on International Narcotics Control

HDMA
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Marino/Blackburn Legislation

Original bill modified and reintroduced. We successfully secured Democratic co-sponsors with several concessions from the original legislation.

- Still contains provisions related to corrective action plans and definition of terms.
- Removed provisions requiring drug testing and background checks.
- Reformulated working group concept now to be a joint report from FDA/CDC on federal efforts to address Rx abuse and potential impact of these efforts on patients and supply chain entities.

HDMA
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Meeting with Attorney General

Congressman Marino sent a letter to U.S. Attorney General Eric Holder requesting a meeting with representatives from the pharmaceutical supply chain to discuss improving collaboration with the DOJ and DEA "to work together to significantly curtail the abuse of prescription drugs."

- The meeting has been scheduled for June 9, 2014
- The logistics are TBD, but Rep. Marino would like representatives from HDMA, NACDS and NCPA to attend with outside counsel fully versed in the CSA*

(*) Congressman Marino specifically requested Linden Barber, former Associate Chief Counsel for DEA, now with Quarles & Brady LLP

HDMA
Healthcare Distribution Management Association

GAO Survey of Distributors

At the direction of a bi-partisan group of Senators, the Government Accountability Office (GAO) is in the process of finalizing a survey to assess the effectiveness of the federal government, particularly the DEA, in its efforts to reduce prescription drug abuse. GAO is attempting to gauge distributor perspectives on:

- Interactions with DEA
- The helpfulness of DEA's guidance and resources
- Impact on DEA enforcement actions on business practices

GAO indicated that they hope to have this report completed in the Fall of 2014.

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Alliance to Prevent the Abuse of Medicines

The Alliance developed a "Legislative Concepts" document that is currently being circulated with key members of congress. The objective is to build momentum in the Congress to encourage a comprehensive approach to addressing Rx abuse and diversion.

- The Alliance held a policy briefing in April which featured representatives from each of the participating organizations and was hosted by Energy & Commerce Health Subcommittee Chairman Joe Pitts (R-PA) and Ranking member Frank Pallone (D-NJ).

HDMA
Healthcare Distribution Management Association

NABP Stakeholder Group

HDMA has been invited to participate in an NABP hosted Healthcare Stakeholder group to address prescribing and dispensing of controlled substances.

- The group issued a consensus statement in February indicating that it was working toward improving coordination among stakeholders – primarily between prescriber and pharmacy groups.
- Two draft "red flag" documents are in the process of being finalized: 1.) warning signs for prescribers, 2.) warning signs for pharmacists dispensing controlled substances
- The group will meet next in July at NABP to finalize these documents and work on a document to outline steps to improve dialogue so the red flags can be addressed collaboratively

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Healthcare Distribution Management Association

DEA – Hydrocodone Combination Products (HCPs)

- Proposal to place HCPs into Schedule II
- Results in label/labeling changes, certain prescribing limitations, **storage in vaults**
- HDMA written comments 4/28 - concerns about vault construction timing. Requested:
  - At least 12-24 months to expand vaults
  - Allow contracts/plans to demonstrate compliance; include a process for this
  - Uncertainties - more time may be needed

HDMA
Healthcare Distribution Management Association

LIFO Repeal

LIFO Repeal

Repeal of the LIFO accounting standard was broached as a potential "pay-for" in both House and Senate Tax Reform proposals. Fortunately, neither proposal is likely to get traction this year.

- HDMA continues to work with the LIFO Coalition to oppose LIFO Repeal.
- NAW wants to engage in a campaign to cultivate grassroots opposition to LIFO Repeal. <u>They have asked HDMA to contribute $10,000.</u>

HDMA
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State Legislative/Regulatory Update

Healthcare Distribution Management Association

Prescription Drug Abuse/Controlled Substances

Distributor Notification Legislation

- In Maryland, HDMA defeated burdensome, first of its kind legislation, that would have required wholesalers to notify pharmacies of any limitation in ordering or availability of drug products.

Suspicious Orders

- Onerous legislation in Tennessee was amended to include industry supported suspicious orders requirements that wholesalers currently do for DEA.

Controlled Substance Scheduling

- Five states (WV, IL, TN, IN, SC) introduced bills proposing to list PSE in Sch. III, none are expected to pass. Storage/handling exemptions were secured in all.
- Louisiana legislation to make Soma a Sch. II CS is expected to pass. HDMA storage/handling exemption was amended into the bill.

Drug Abuse Task Forces

- HDMA is monitoring and attending when possible several different state drug abuse task forces across the country.

Disposal/Product Stewardship

- Alameda County, CA product stewardship program still on appeal in the 9th U.S. District court.
- California SB 1014, which proposed statewide requirements similar to Alameda County, was amended in favor of industry efforts to delete product stewardship requirements.
- Other states and municipalities are awaiting the outcome of the Alameda case before proceeding with similar initiatives.
- PHRMA has formed a Product Stewardship Council to address these issues as they arise.

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DSCSA Implementation/State Preemption

California

- E-pedigree requirements immediately preempted

Oklahoma

- HDMA participating in Board of Pharmacy Task Force reviewing state wholesaler statute/regs.

Florida

- Dept. prefers to issue individual Declaratory Statements in response to preemption questions.
  - Each of the three issued so far recognize federal preemption of Florida pedigree requirements.

Other states are expected to address their preempted requirements in the near future.

HDMA
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Gross Receipts Tax

Earlier this year **Ohio** Gov. Kasich, as part of an effort to reduce state income taxes, proposed an increase in the State's Commercial Activity Tax (CAT) from .26 to .30%.

- HDMA has re-engaged our lobbyist in Columbus to coordinate efforts among our Ohio members to defeat this legislation.

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Questions?

Healthcare Distribution Management Association

HDMA DSCSA Implementation 2014 Activities

Updated 05/21/14

Legend [Box] Green = In Progress Purple = Meeting/Call Blue = Complete
Red = Deadline Yellow = On Hold/TBD

P:\GA\REGULATORY\RETAIN\FDA\DQSA\Gantt

For HDMA Distributor Members Only - Please Do Not Circulate

MONTH	APR				MAY				JUN					JUL
(MON)DAY	07	14	21	28	05	12	19	26	02	09	16	23	30	07
FDA Suspect and Illegitimate Product Guidance														
HDMA Letter Submitted to FDA	**<- Feb. 24**													
FDA Guidance Statutory Deadline								**Due May 27**						
Wholesalers required to have systems in place													**Due 1-1-15 ->**	
Traceability Implementation Work Group Meeting	**<- Jan. 8**		**Feb. 5**	**Mar. 5**	**Apr. 2**		**Apr. 30**							**Jul. 9**
Review PDSA Material														
Manufacturer FAQs					**Initial Review**		**Review revision**							
Review 3PL licensure draft											**TBD**			
Draft Transaction Statements						**Review**								
TI/TH/TS Requirements (1/1/15)														
FDA Guidance on Standards													**Due 11-27-15 ->**	
Wholesalers Required to Transmit													**On 1-1-15 ->**	
Review PDSA RFI response comment letter		**Complete Apr. 16**												
Submit RFI Response to FDA		**Submitted Apr. 18**												
FDA Standards Workshop & Follow Up					**May 8-9**					**Due June 9**				
HDMA-FDA Meeting								**TBD**						
FDA process - grandfathering, waivers, identifiers, etc.										**Discuss**			**Due 11-27-15 ->**	
Process Flows and Matrices														
Rework flows					**Discuss and Finalize**									
Ex. Distributor & Direct Purchase Repackager							**Discuss**							
856 EDI Standards Updated				**Complete Apr. 30**									**Revision**	**TBD ->**
Reporting State Licensure													**On 1-1-15 ->**	
Submit HMDA Recommendations to FDA						**Revise Draft Spreadsheet, Discuss and Finalize**								
FDA to release guidance												**TBD**		
FDA Rule On State Licensure Standards													**Due 11/27/15 ->**	
Licensure recommendations						**Revise Draft Options**						**Submission TBD**		
Discuss and agree on requirements							**Review**							
3rd party inspection recommendations (VAWD)				**Discuss**							**Review**			
Submission to FDA										**TBD**				
HDMA Preemption Letter to States	**<- Jan. 17**		**Ongoing Discussions**			**Discuss - NABP**			**Ongoing Discussions**					
New Product Introduction Form						**Discuss and Finalize**								
3PL Licensure Preemption Analysis/Options			**On Hold**											

.....

(Original Signature of Member)

113TH CONGRESS
2D SESSION

H. R. _____

To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. MARINO (for himself, Mrs. BLACKBURN, Mr. WELCH, and Ms. CHU) introduced the following bill; which was referred to the Committee on _____

A BILL

To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Ensuring Patient Access and Effective Drug Enforcement Act of 2014".

SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED SUBSTANCES ACT.

(a) DEFINITIONS.—

(1) CONSISTENT WITH THE PUBLIC HEALTH AND SAFETY.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

"(j) In this section, the phrase 'consistent with the public health and safety' means having a substantial relationship to this Act's purpose of preventing diversion and abuse of controlled substances.".

(2) IMMINENT DANGER.—Section 304(d) of the Controlled Substances Act (21 U.S.C. 824(d)) is amended—

(A) by striking "(d) The Attorney General" and inserting "(d)(1) The Attorney General"; and

(B) by adding at the end the following:

"(2) In this subsection, the term 'imminent danger' means a significant and present risk of death or serious bodily harm that is more likely than not to occur in the absence of an immediate suspension order.".

(b) OPPORTUNITY TO SUBMIT CORRECTIVE ACTION PLAN PRIOR TO REVOCATION OR SUSPENSION.—Section 304(c) of the Controlled Substances Act (21 U.S.C. 824(c)) is amended—

(1) by striking "(c) Before" and inserting "(c)(1) Before"; and

(2) by adding at the end the following:

"(2) Before revoking or suspending a registration pursuant to section 303, the Attorney General shall—

"(A) provide—

"(i) notice to the registrant of the grounds for revocation or suspension; and

"(ii) in the case of any such grounds consisting of a violation of law, a specific citation to such law;

"(B) give the registrant an opportunity to submit a corrective action plan within a reasonable period of time to demonstrate how the registrant plans to correct the grounds for revocation or suspension; and

"(C) determine whether—

"(i) in light of the plan, revocation or suspension proceedings should be discontinued or deferred; or

"(ii) additional changes need to be made in the corrective action plan.".

SEC. 3. REPORT TO CONGRESS ON EFFECTS OF LAW ENFORCEMENT ACTIVITIES ON PATIENT ACCESS TO MEDICATIONS.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and

Human Services, acting through the Commissioner of the Food and Drugs and the Director of the Centers for Disease Control and Prevention, and in consultation with the Administrator of the Drug Enforcement Administration and the Director of National Drug Control Policy, shall submit a report to the Congress—

(1) assessing how patient access to medications could be adversely impacted by Federal and State law enforcement activities; and

(2) identifying how collaboration between agencies and stakeholders can benefit patients and prevent diversion and abuse of controlled substances.

(b) CONSULTATION.—The report under subsection (a) shall incorporate feedback and recommendations from the following:

(1) Patient groups.

(2) Pharmacies.

(3) Manufacturers of drugs.

(4) Common or contract carriers and warehousemen.

(5) Hospitals, physicians, and other health care providers.

(6) State attorney generals.

(7) Law enforcement officials, including local law enforcement officials.

(8) Health benefit plans and entities that provide pharmacy benefit management services on behalf of a health benefit plan.

(9) Wholesale drug distributors.

TOM MARINO
10TH DISTRICT, PENNSYLVANIA

COMMITTEE ON THE JUDICIARY

COMMITTEE ON HOMELAND SECURITY

COMMITTEE ON FOREIGN AFFAIRS

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April 30, 2014

The Honorable Eric H. Holder, Jr.
Attorney General of the United States
Robert F. Kennedy Building
950 Pennsylvania Avenue, NW
Washington, DC 20530-2000

Dear General Holder:

Thank you for your appearance before the House Judiciary Committee on April 8 for the Committee's Department of Justice oversight hearing. In the final minutes of what was otherwise at times a contentious hearing, I appreciated our constructive exchange on what is a very serious national problem - the diversion and abuse of prescription drugs. The purpose of this letter is to follow up on that discussion.

I believe strongly that industry stakeholders and government regulators have a responsibility to work together productively to address this tragic epidemic. As you are aware, I have introduced legislation to enhance such collaboration with goals that include (a) identifying gaps and opportunities to ensure the safe use of prescription drugs with the potential for diversion and abuse; (b) developing recommendations on specific ways to reduce the diversion and abuse of prescription drugs; and (c) reaching the right balance that ensures access by individuals to prescription drugs for legitimate medical purposes.

I was very pleased the hear that you would welcome a conversation with legitimate companies in the pharmaceutical supply chain that would focus on the ways in which these companies and the Department of Justice, the DEA and other interested parties could work together to significantly curtail the abuse of prescription drugs. These companies, of course, have the affirmative responsibility to take steps to reduce these abuses. I was also pleased that you recognized that there are many individuals who have legitimate needs for certain prescriptions that, for example, relieve pain. To this end, it is important that legitimate businesses operating in the pharmaceutical supply chain be governed by laws and regulations that clearly convey the expectations of Congress and the Department.

At the hearing, you suggested that I facilitate this conversation, so I plan to follow up with appropriate members of your staff to schedule a meeting. Your direct, personal leadership and guidance on this joint effort is essential to seeing that significant progress be made to address this tragic national problem. Because a visible commitment at the highest levels of the Department is

critically important, I encourage you also to involve Deputy Attorney General Cole in our meeting and, thereafter, in the work going forward.

I am aware that both you and President Obama have stated publicly that we cannot arrest our way out of the drug problem. If that is the case, I believe that the time to engage in other strategies to meet this daunting challenge is now. I hope that our conversation at the April 8 hearing can open the door to a more positive working relationship between the Department of Justice and legitimate businesses which enhances America's strategy to prevent prescription drug abuse.

Thank you again. I look forward to working with you further on this vitally important issue.

Sincerely,

Tom Marino

Tom Marino
Member of Congress

It would be great to work together on this. - Tom

Alliance to Prevent the Abuse of Medicines

LEGISLATIVE CONCEPTS

I. <u>Public Health Approach</u> -- *The Alliance supports a public health approach to preventing the abuse of medicines by placing a premium on prevention, early identification of abuse, and treatment through promotion of public health tools such as widespread adoption of drug courts and Medicaid adoption of prescription drug abuse screening tools coverage, such as SBIRT, or other patient intervention and treatment approach.*

- Expansion of national and community-based prescription drug abuse prevention programs in schools, communities and the workplace.
- Ensure and evaluate access to coverage of prescription drug abuse treatment by insurers, exchanges, Medicaid and Medicare to cover treatment for prescription drug abuse and addiction per Mental Health Parity Act and Affordable Care Act requirements.
- Target and expand funding and resources to prescription drug abuse prevention and treatment.
- Department of Justice to conduct an analysis of states where drug courts have been successful in decreasing prescription drug abuse and lowering costs associated with prosecution and incarceration, and then establish a federal plan, which implements identified best practices nationwide so states can adopt.
- Coordinate the law enforcement associated with drug courts with federal and state prescription drug treatment programs and public health agencies to improve likelihood of early intervention and rehabilitation.
- Encourage the U.S. Department of Health and Human Services (HHS), National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), National Institute on Alcohol Abuse and Alcoholism (NIAAA), and Substance Abuse and Mental Health Services Administration (SAMHSA), to conduct research regarding the effectiveness of applying the SBIRT model to prescription drug abuse (currently utilized predominantly for alcohol and tobacco).
- HHS to provide grants to states to ensure national coverage of Screening, Brief Intervention, and Referral to Treatment Coverage (SBIRT), or similar patient treatment approach, as an intervention protocol for early prevention and treatment at all places of patient care. HHS to provide communication to providers of the availability of non-Medicaid reimbursement for SBIRT, and require Medicaid coverage of treatment for patients referred through SBIRT or similar patient intervention program, including access to specialty care.
- HHS to target seven states where prescription drug abuse is prevalent and to provide grant dollars to those states to train health care professionals in early detection and treatment of prescription drug abuse.

II. <u>Improve the Effectiveness of Prescription Drug Monitoring Programs (PDMPs)</u> -- *The Alliance believes that each state should operate an effective, interoperable and up-to-date PDMP that is integrated into prescriber and pharmacist workflow, and provide for prescriber notification and education in outlier cases.*

- The Alliance supports a Government Accountability Office (GAO) study to evaluate research-based evidence that demonstrates PDMP effectiveness, relating to the various characteristics of PDMPs (timely data collection/reporting and accessibility of this information by prescribers, pharmacists and their respective designees and information sharing among states, doctor shopping thresholds, PMP staff size, etc.) to outcomes
- Advocate for solutions that provide prescribers, their proxies where allowed under state law, and pharmacists with patient-specific, timely updated information at the point-of-care for the purpose of improving public health.
- Support full funding and staffing for up-to-date, and interoperable prescription drug monitoring programs at the point-of-care that are integrated into a prescriber's and pharmacist's workflow.
- Require each state to have an effective interoperable and timely updated Prescription Drug Monitoring Program, which should ideally include integration of PDMP data into electronic health records (EHRs). The PDMP should identify the patient and the prescriber.
- Encourage adoption of National Association of Boards of Pharmacy (NABP) Interconnect program to apply nation-wide and to allow uniform access guidelines for PDMP programs across state lines.

The Alliance supports the components of a strong prescription drug-monitoring program. Certain effective PDMP components, as set forth by the National Association of Model State Drug Laws (NAMSDL), should be as follows:

- The PDMP would monitor federal controlled substances, additional specified controlled substances regulated by the state, and drugs of concern documented to demonstrate a potential for abuse, particularly those identified by law enforcement and addiction treatment professionals.
- The PDMP would improve patient care by proactively providing reports to educate prescribers and dispensers on instances of overuse by patients.
- The PDMP would support the safe practice of medicine by generating reports to prescribers in instances where prescribing patterns fall outside of expected norms (controlled for practice specialty or patient populations). PDMP programs should provide these prescribers with data identifying their prescribing patterns and, if necessary, direct those physicians to educational resources on the appropriate prescribing of controlled substances. Prescribers who are not responsive to program efforts or who continue an unexplained pattern of prescribing after being contacted by the program will be referred to the appropriate state medical licensing authority for further investigation.
- The PDMP statute should allow the Administrator to disclose de-identified data for statistical, public research, public policy or educational purposes. Prior to disclosure, the Administrator should remove all information, which identifies, or could reasonably be used

to identify, the patient, prescriber, dispenser or other person who is the subject of the information.

- The individuals or officials allowed to request specific data from the program should include prescribers, dispensers and health care licensing boards that regulate prescribers and dispensers.
- Requestors of PDMP information are required to prove that they have the education, training and instruction necessary to responsibly and properly use the data, as well as prove they fall within a designated category of authorized requestors. Health licensing agencies must establish a uniform standard for designating authorized requestors of PDMP.
- State officials, by statute, regulation, rule or policy, or in practice, should establish an appropriate linkage from the PDMP to addiction treatment professionals to help individuals identified through the PDMP as potentially impaired or potentially addicted to a substance monitored by the PDMP.
- Each state should provide for appropriate interstate sharing of PDMP data by statute, regulation or interstate agreement. Recipients of PDMP data from other states may include prescribers, dispensers, health care licensing boards that regulate prescribers and dispensers, PDMP officials or other specified authorities, subject to privacy and other standards of the supplying state.
- PDMP data should not be subject to public or open records law.
- The PDMP should include: an evaluation component that identifies the cost benefits of the PDMP; impacts of the use of the data on the practices of authorized users; and, any recommended operational improvements and other information relevant to policy, research and education involving controlled substances and other drugs of concern monitored by the PDMP. As part of the ongoing assessment process, an advisory committee or designated individuals should provide advice and input regarding the development and operation of the PDMP.

III. <u>Abuse Deterrent Technology</u> -- *The Alliance supports the Food and Drug Administration (FDA) to require generic versions of extended-release, long acting opioids to have abuse-deterrent properties that are equal in effectiveness, but not necessarily identical to the brand. Abuse deterrent technology is an important and effective tool that should be used to help address prescription drug abuse, and should be incentivized for manufacturers to advance the development of this technology.*

- Require FDA to be the arbiter of what is an effective deterrent.
- FDA to take into account the continued evolution of abuse deterrence technology, and the need for these products to prove abuse deterrence by increasing the safe use of a product and to prevent abusers from being able to "easily circumvent" the protective measures of a product.
- FDA to establish parameters for approval of generic abuse deterrent formulations.
- Require abuse deterrent technology for generic products to be as effective as, but not necessarily identical to, the brand reference product.

IV. <u>Eliminating Pill Mills</u> -- *The Alliance supports enforcement actions to halt "pill mill" activities through legislation that develops standards for pain management clinics and assists prescribers with guidelines on how to prescribe painkillers safely and effectively.*

- Establish guidelines for prescribers and pharmacists to help them identify potential abusers and diverters of controlled substances to help ensure the safe and effective prescribing and dispensing of opioids and other controlled substances.
- HHS to conduct a study of best practices in states regarding statutes and guidelines on regulating pain management clinics. Develop state model laws/guidelines based on study findings of best practices and encourage states to adopt state model.

V. <u>Education on Prescription Drug Abuse</u> -- *The Alliance supports education for the public – consumers, patients and all stakeholders – to stop this public health epidemic and help prevent new cases of abuse.*

- Authorize Department of Health and Human Services to conduct nationwide public education campaign on prescription drug abuse.

VI. <u>Medicaid Pharmacy Lock-In Program</u> -- *The Alliance recommends improving State Medicaid pharmacy "Lock-In" programs as an avenue for States to prevent and fight the abuse of prescription medicines by Medicaid beneficiaries.*

- Require Medicaid programs to establish a "Lock-In" program under which procedures are designed to prevent fraud and abuse in the dispensing and prescribing of certain controlled substances to high users, including restricting the beneficiary to obtain prescriptions from only one pharmacy.
- Establish exceptions to Medicaid beneficiaries in areas such as rural regions where access to pharmacies is limited.

VII. <u>Medicare Pharmacy Lock-In Program</u> -- *The Alliance is currently evaluating prescription drug abuse within the Medicare program and is determining how to curb abuse in Medicare Part D plans. The Alliance is reviewing how to appropriately implement a Medicare Lock-In program.*

- Restrict beneficiaries who are suspected of abusing certain medications to obtain prescriptions from only one pharmacy.
- CMS should establish protections for beneficiaries to ensure that access to needed medications is not disrupted.

VIII. <u>Enhance Oversight of Controlled Substances and Establish Prescription Drug Abuse Working Group</u> -- *The Alliance supports bringing greater clarity to the requirements for the safe and secure distribution and dispensing of controlled substances and establishment of a prescription drug abuse working group to report to Congress.*

- Clarify existing authorities under the Controlled Substances Act (CSA). Implement a process to identify and mitigate concerns pertaining to the distribution and dispensing of controlled substances.

- Ensure that any imposed restrictions regarding the continued distribution of controlled substances are not performed in an overly broad manner such that they adversely affect patient care and access.
- Require registrants to obtain criminal background checks and drug tests on each non-licensed health care professional , such as warehouse workers of distributors or manufacturers, who has or will have access to controlled substances. Licensed healthcare professionals such as prescribers and dispensers would be exempted from this section's requirements.
- The bill requires the Attorney General to give the registrant an opportunity to submit a corrective action plan that demonstrates how the registrant plans to correct the grounds for revocation or suspension and for the Attorney General to then determine whether, in light of the plan, revocation or suspension proceedings should be discontinued or deferred.
- The President to establish a Working Group comprised of governmental sector leaders, industry sector leaders and advocates to review and report to Congress on federal policies to reduce prescription drug diversion and abuse and make recommendations on specific ways to address the epidemic.

IX. **Take Back Program Proposal** – ***The Alliance seeks to decrease the supply of diverted prescription drugs, and, to that end, supports the appropriate removal of unused, unneeded or expired prescription drugs, including controlled substances, from medicine cabinets and out of the reach of potential abusers, and federal funding for a national framework to support accessible state-level Take Back locations. The Alliance puts forth the following guidance to ensure an effective Take Back program under the DEA proposed rule:***

- The requirements of voluntary participation in Take Back should not be prohibitively burdensome with respect to cost, liability, or compliance hurdles, so as to deter participation and therefore limit the usefulness of the program.
- Any proposed rule offered by DEA implementing the drug disposal statute should be harmonized with other federal agency rules (see EPA, OSHA, FDA, DOT), as well as state requirements.
- A proposed DEA rule should ensure expansion of the program to allow for additional federal agencies, e.g., DOD, VA, to participate in the program.
- DEA, in conjunction with other federal agencies participating in the Take Back program, should from time to time study the effectiveness of the program comparative to the prescription drug epidemic to evaluate whether the program is having a mitigating effect. Such evaluation should ensure that the economic and environmental impacts of the program remain minimal.

* * *

HDMA Board of Directors

Tab H – Dashboard Review

HDMA Issues / Initiatives
Dashboard - First Quarter 2014

Q1 2014
Updated: 2/18/14 - COUNCIL PROPOSED

Initiative	Status							
	FGA	SGA	Reg	IR	PA	Cntr	Edu	SBDC
A Priorities								
340B Issues	2			2				2
Biotechnology / Specialty				1	1	1	1	1
Controlled Substance Issues	1	1	1	2	1		2	
Distributor Licensing / Accreditation	~~1~~ 2	1	1		1			
Drug Shortages / Product Availability	1	2	2	2	1		1	1
Generic Drugs: Issues	2	2		2	2	2		
Healthcare Standards (Serialization, etc.)			1	1	2	2	1	
Importation / Import Safety	1	2			1			
Supply Chain Security	2	1	2	1	1	1	1	
Marketing and Gift Restrictions		2	1					
Medicaid: AMP / RSP / AAC / WAC	~~1~~ 2	2	1		1		1	1
Medicare: Part B ASP (Prompt pay/CAP)	1		2		2			1
~~Pedigree~~ Traceability Requirements	1	1	~~2~~ 1	1	1	1	1	1
Pseudoephedrine / Dextromethorphan	2	1						
Rx Waste / Disposal / Take-Back	2	1	1	2		1	1	
Tax Issues (Gross Receipts and LIFO)	1	1			1			
Wholesaler Price Reporting		1	2					
B Priorities								
Cold Chain Best Practices			2	1		2	1	2
Conditions for Safe Use			2					
Contract Administration				1			1	
Counterfeiting Alert Network (CAN)			2		1			
DOT Issues			1					
EDI Guideline Updates				1			1	
Emergency Preparedness / Pandemic Influenza	2	2	2	1	2		2	
Health, Beauty & Wellness				1	2		2	
NDC Rule (Repackaging/Relabeling)			2		2			
Non-Approved Drugs			1					
PBM Transparency	2	2						
Returned Goods		1	1	1	2	1	1	
Risk Eval Mitigation Strategies (REMS)	2		2	1	2	1	2	
Role of Distributor Study					1	1		
Seasonal Influenza	2	2	2	2	2			

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HDMA Issues / Initiatives
Dashboard - First Quarter 2014

Q1 2014
Updated: 2/18/14 - COUNCIL PROPOSED

Initiative	Status							
	FGA	SGA	Reg	IR	PA	Cntr	Edu	SBDC
C Priorities								
Bar Code Rule			2					
Future of Healthcare Study						2		
Health IT	2		2		2	2		
Internet Pharmacy	2		2					
Labor / Card Check	2		2					
Patient Privacy/HIPAA	2	2	2		2			

Long Term Consideration

	Date Added	Notes
Consolidation	4/6/2007	
Future of Pharmacy (Pharmacy 2020)	4/6/2007	
Health IT	4/6/2007	
International Distribution	4/6/2007	
Risk Management	4/6/2007	
Sustainability/Corporate Social Responsibility	8/10/2007	
Vertical Integration	4/6/2007	

Removed

	Date Removed	Reason
856 Ship Notice w/ Healthcare Product Data	2/3/2011	Contained in EDI and Healthcare Standards
1099 Reporting	8/1/2011	Issue resolved
BioShield Reauthorization	2/7/2007	Issue resolved
Data Management Study	2/3/2011	Contained in Healthcare Stds and Pedigree
DEA CSOS: EDI Guidelines	4/6/2007	All related issues now under DEA CSOS
DEA Fees	4/6/2007	Combined with DEA Rules
DME Accreditation / Surety Bond	9/15/2010	
DOD - Tricare	2/7/2007	Issue resolved
Generic Drugs: EPC / RFID Cost-Benefit	4/6/2007	Contained under Rx SafeTrack
Generic Drugs: Settlements/Reimbursement	4/6/2007	Combined under Generic Drug Issues
Healthcare Reform (non-HDMA priorities)	1/28/2011	Bill signed into law in 2010
Medicare Part D / Price Negotiation / Other	9/15/2010	
PDMA Regulations and Requirements	2/7/2007	Combined with Pedigree Requirements
PDUFA (Rx Manufacturer User Fees)	7/2/2007	
Repackaging	2/7/2007	Combined with NDC Rule
Rx SafeTrack	1/28/2011	Formal effort no longer operating
State Bulk Purchasing	8/1/2008	No state activity
Thymerisol	7/2/2007	
Track & Trace Standards	2/7/2007	Combined into EPC Standards

STATUS: 1 = Active Project or Issue; 2 = Monitoring / Emerging
PRIORITY: A = High for organization and/OR industry; B = Medium; C = Low

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HDMA Board of Directors

Tab I – Executive Committee Budget

Breakout Group Reports

HDMA
Healthcare Distribution Management Association

MEMORANDUM

TO: HDMA Board of Directors

FROM: John M. Gray

DATE: May 22, 2014

RE: HDMA FUTURE YEARS' BUDGETS: 2015 to 2020

Overview

Since its meeting at the end of February, the Executive Committee has been taking a deep dive into HDMA's budget in order to assess projected future resource needs and ensure sufficient revenue in future years to meet those needs.

As shared with the Executive Committee last February, HDMA's operating expenses are currently expected to increase approximately 4% each year, with zero to 2% annual increases in projected revenue. This results in continued pressure to reduce operating expenses, raise members' dues and find additional sources of revenue.

Process

The overarching goal of the project is to recommend a path forward to address HDMA's projected budget shortfalls for years 2015 through 2020 so that we avoid the "repetitive dialogue" on how to balance the budget each year.

To best accomplish this, the Executive Committee organized into three workgroups, each with its own sub-goals, as detailed below:

1) Domestic Revenue/Business Development group
   - Dave Moody
   - Dave Neu
   - Ted Scherr

   Goal: Develop a plan to provide adequate revenue for HDMA to accomplish its mission and meet member needs through 2020 by formulating, evaluating and recommending:
   - Potential new U.S. revenue sources
   - A reserve fund spending policy
   - Whether/how to increase member dues

2) International Revenue/Business Development group
   - Ken Couch
   - Mark Walchirk

   Goals:
   - Formulate, evaluate and recommend potential HDMA revenue sources outside of the U.S.
   - Evaluate the future role of IFPW with respect to HDMA - formal or informal alignment?
   - Recommend new name for HDMA that captures international component

3) Expenses group
   - Mike Kaufmann
   - Dale Smith

   Goal: Review HDMA's expenses and develop recommendations for increases/reductions in spending and/or shifts in resource allocation that will enable HDMA to best accomplish its mission and meet member needs through 2020.

A series of conference calls has taken place over the last three months for each group to undertake its work. There will be further discussion at the upcoming Executive Committee meeting on June 1st, with final recommendations expected for the Executive Committee and Board meetings at the Annual Board & Membership Meeting (ABMM) at the end of September.